SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

K070162

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LigaSure™ Vessel Sealing System

1. Submitter Information

Valleylab
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MAR 06 2007

Date summary prepared: January 16, 2007

2. Name of Device

Trade or Proprietary Name: ForceTriad™ Electrosurgical Generator

Common/Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories

3. Predicate Devices

The ForceTriad™ Electrosurgical Generator is substantially equivalent to the following legally marketed medical devices:

- ForceTriad™ Electrosurgical Generator (K051644)

4. Device Description

The ForceTriad™ generator is a full-featured electrosurgical generator with monopolar, bipolar, and Valleylab LigaSure™ vessel sealing outputs. This 510(k) only applies to the LigaSure™ Vessel sealing portion of the generator. The generator is electrically isolated, microcontroller-based device, incorporating closed-loop control for all output modes implemented in the microcontroller firmware. The generator incorporates Instant Response™ technology to constantly measure the electrical impedance of the tissue and instantaneously adjust the generator output to maintain the desired power.

The generator is used with a selection of instruments designed for use with the ForceTriad and the LigaSure Vessel Sealing generator. All of the instruments are capable of sealing vessels up to, and including, 7mm, and tissue bundles as large as can fit in the jaws of each instrument. When a LigaSure™ instrument is applied to a vessel or tissue bundle and RF energy is applied, the collagen and elastin in the tissues are reformed by heat and pressure to fuse vessel walls, thereby forming a permanent seal. The microprocessor in the generator monitors the tissue properties, stops the

application of energy, and allows a brief period of cooling before indicating that the seal cycle is complete.

No changes are being made to the design or operation of any of the devices within the current system. The change as proposed in this 510(k) notification is to the intended use as described above and the resulting labeling changes.

5. Intended Use

The ForceTriad™ is a full-featured electrosurgical generator intended for open and laparoscopic surgical procedures where the surgeon requires electrosurgical cutting, coagulation, or vessel sealing (tissue fusion). The generator is intended for use in general, laparoscopic and gynecologic surgical procedures where ligation of vessels, pulmonary vasculature, or lymph vessels, is desired. The system creates a vessel ligation (seal) by the application of bipolar electrosurgical RF energy (coagulation) to vessels interposed between the jaws of the device. The generator can also be used with standard bipolar devices where bipolar cutting or coagulation is desired.

The indications for use include general (including urologic, thoracic, plastic and reconstructive), laparoscopic, and gynecological procedures where electrosurgical cutting and coagulation of tissue, and sealing (fusion) of vessels, including pulmonary vessels, and tissue bundles is performed, including such procedures as bowel resections, hysterectomies (both vaginal and abdominal), laparoscopic cholesystectomies, laparoscopically assisted vaginal hysterectomies, gall bladder procedures, Nissen fundoplication, adhesiolysis, oophorectomy, etc. The devices can be used on vessels (arteries, veins, pulmonary arteries, pulmonary veins, lymph) up to 7mm and bundles as large as will fit in the jaws of the instruments.

The LigaSure tissue fusion function has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use this function for these procedures.

6. Summary of Technological Characteristics

The technological characteristics of the ForceTriad Electrosurgical generator have not been modified.

7. Performance and Clinical Data

Pre-clinical studies (acute and chronic) and bench testing have shown that the ForceTriad Electrosurgical Generator effectively seals pulmonary vasculature, producing seals with burst pressures substantially greater than the physiologic pressures in the vessels.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Valleylab, a Division of Tyco
Healthcare Group LP
% Mr. Philip E. Ake
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5920 Longbow Drive
Boulder, Colorado 80301

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Re: K070162
Trade/Device Name: Force Triad™ Electrosurgical Generator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: January 16, 2007
Received: January 17, 2007

Dear Mr. Ake:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K070162

Device Name: ForceTriad™ Electrosurgical Generator

Indications For Use:

The ForceTriad™ is a full-featured electrosurgical generator intended for open and laparoscopic surgical procedures where the surgeon requires electrosurgical cutting, coagulation, or vessel sealing (tissue fusion). The generator is intended for use in general, laparoscopic and gynecologic surgical procedures where ligation of vessels, pulmonary vasculature, or lymph vessels, is desired. The system creates a vessel ligation (seal) by the application of bipolar electrosurgical RF energy (coagulation) to vessels interposed between the jaws of the device. The generator can also be used with standard bipolar devices where bipolar cutting or coagulation is desired.

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Prescription Use ✓ AND/OR Over-the-Counter Use ____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices